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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/473,551	12/28/99	MILBRANDT J	6029-9879

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Elie H Gendloff
Howell & Haferkamp LC
7733 Forsyth Boulevard
Suite 1400
St. Louis MO 63105

EXAMINER	
CHERNYSHEV,O	
ART UNIT	**PAPER NUMBER**
1646	10

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/473,551	Applicant(s) MILBRANDT ET AL.	
	Examiner Olga N. Chernyshev	Art Unit 1646	

-- The MAILING DATE of this communication appears on th cover sh et with th correspond nc address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims 1-36 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, drawn to a growth factor, which activates GFRα1-RET, classified in class 530, subclass 399, for example.

II. Claims 10-20, drawn to nucleic acids and recombinant methods of protein production, classified in class 536, subclass 23.51, for example.

III. Claims 21-23, drawn to a method of providing trophic support to a cell by treatment with a growth factor, classified in class 435, subclass 377, for example.

IV. Claims 21-23, drawn to a method of providing trophic support to a cell by treatment with a nucleic acid, classified in class 514, subclass 44, for example.

V. Claims 21, 23, 24, 25, 28, drawn to a method of providing trophic support to a cell by implanting a cell, classified in class 424, subclass 93.1, for example.

VI. Claim 26, drawn to a method of treating cellular degeneration by treatment with a growth factor, classified in class 435, subclass 375, for example.

VII. Claim 26, drawn to a method of treating cellular degeneration by treatment with a nucleic acid, classified in class 514, subclass 44, for example.

VIII. Claim 26-27, drawn to a method of treating cellular degeneration by implanting a cell, classified in class 424, subclass 93.1, for example.

IX. Claim 29, drawn to a growth factor which activates GFRα1-RET and GFRα2-RET, classified in class 530, subclass 399, for example.

X. Claim 30, drawn to nucleic acids and recombinant methods of protein production, classified in class 536, subclass 23.51, for example.

XI. Claim 31, drawn to a method of providing trophic support to a cell by treatment with a growth factor, classified in class 435, subclass 377, for example.

XII. Claim 31, drawn to a method of providing trophic support to a cell by treatment with a nucleic acid, classified in class 514, subclass 44, for example.

XIII. Claim 32, drawn to a method of treating cellular degeneration by treatment with a growth factor, classified in class 435, subclass 375, for example.

XIV. Claim 32, drawn to a method of treating cellular degeneration by treatment with a nucleic acid, classified in class 514, subclass 44, for example.

XV. Claim 33, drawn to a growth factor which activates GFRα1-RET and GFRα3-RET, classified in class 530, subclass 399, for example.

XVI. Claim 34, drawn to nucleic acids and recombinant methods of protein production, classified in class 536, subclass 23.51, for example.

XVII. Claim 35, drawn to a method of providing trophic support to a cell by treatment with a growth factor, classified in class 435, subclass 377, for example.

XVIII. Claim 35, drawn to a method of providing trophic support to a cell by treatment with nucleic acid, classified in class 514, subclass 44, for example.

XIX. Claim 36, drawn to a method of treating cellular degeneration by treatment with a growth factor, classified in class 435, subclass 375, for example.

XX. Claim 36, drawn to a method of treating cellular degeneration by treatment with a nucleic acid, classified in class 514, subclass 44, for example.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions (I, IX, XV) and (II, X, XVI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Groups (II,X,XVI) and polypeptides of Groups (I,IX,XV) are distinct inventions because they are physically and functionally distinct chemical entities, and the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be used for the processes other than the production of the protein, such as nucleic acid hybridization assay.

3. Inventions I, IX and XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to chemically, structurally and functionally different compounds, which can be made and used without each other, therefore representing patentably distinct inventions.

4. Inventions II, X and XVI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to chemically, structurally and functionally different

compounds, which can be made and used without each other, therefore representing patentably distinct inventions.

5. Inventions III, IV, V, VI, VII, VIII, XI, XII, XIII, XIV, XVII, XVIII, XIX and XX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to different methods that recite structurally and functionally distinct elements, are not required one for the other, achieve different goals, and therefore constitute patentably distinct inventions.

6. Inventions I and (III, V, VI, VIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the growth factors of Group I could be used in an entirely different method, such as in a method of producing antibodies, rather than in methods of Groups (III, V, VI, VIII).

7. Inventions II and (IV, V, VII, VIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Group II could be used in an entirely different method, such as in a method of producing proteins, rather than in methods of Groups (IV, V, VII, VIII).

8. Inventions IX and (XI, XIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the growth factors of Group IX could be used in an entirely different method, such as in a method of producing antibodies, rather than in methods of Groups (XI, XIII).

9. Inventions X and (XII, XIV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Group X could be used in an entirely different method, such as in a method of producing proteins, rather than in methods of Groups (XII, XIV).

10. Inventions XV and (XVII, XIX) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the growth factors of Group XV could be used in an entirely different method, such as in a method of producing antibodies, rather than in methods of Groups (XVII, XIX).

11. Inventions XVI and (XVIII, XX) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Group XVI could be used in an entirely different method, such as in a method of producing proteins, rather than in methods of Groups (XVIII, XX).

12. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter and non-coextensive literature searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. The claims of Groups I-XX are drawn to a multitude of growth factors (SEQ ID NO:1-28), polynucleotides encoding such, and methods of using the growth factor/polynucleotide encoding/cell containing the polynucleotide encoding. This constitutes recitation of an implied, mis-joined Markush group that contains multiple, independent and distinct inventions. Each of the different growth factors/nucleic acids/ and methods of use are independent and distinct because no common structural or functional properties are shared. Burden is established because each growth factor has a unique sequence, and therefore, requires a separate search, as is the

same for the encoding polynucleotide and methods of use. Accordingly, these claims are subject to restriction under 35 U.S.C. § 121.

Upon election of one of Groups I-XX, Applicant is additionally required to elect a single growth factor or polynucleotide (i.e. single molecular embodiment which may be represented by a sequence identifier). This requirement is not to be construed as a requirement for an election of species, since each of the compounds recited in alternative form is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

Species Election

14. In case Group V is elected, this application contains claims directed to the following patentably distinct species of the claimed invention: different pathological conditions (claims 25 and 28).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 24 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-0294 for After Final communications.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)0. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 308-4556 or (703) 308-4242. If either of these numbers is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. Official papers should NOT be faxed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D. *ONC*
May 22, 2001

CHRISTINE J. SAOUD
PRIMARY EXAMINER
Christine J. Saoud